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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,759	06/25/1999	KENICHI HIGASHIYAMA	001560-363	2045

21839 7590 10/30/2002

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/30/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/331,759

Applicant(s)
Higashiyama et al.

Examiner
Irene Marx

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 23, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-12, 14-20, 28-37, and 43-56 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-12, 14-20, 28-37, and 43-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/23/02 has been entered.

Claims 8-12, 14-20, 28-37 and 43-56 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10, 15-17, 43-44, 47-49 and 51-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 fails to find proper antecedent basis in claim 8 for "the nitrogen source"

Claims 51-56 are vague, indefinite and confusing in encompassing an improper Markush grouping because of the use of "and/or" and "or". Proper Markush format is, for example -- selected from the group consisting of A, B, and C--. See MPEP 2173.05(h)(a).

Claims 8-10, 15-17, 43-44, 47-49 are confusing in that the metes and bounds of "subgenus *Mortierella*" are not readily apparent to one of ordinary skill in the art.

Claims 8-10, 15-17, 43-44, and 47-48 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki *et al. et al.* taken with Manoh *et al.* and Yamaguchi *et al.* (US 5,015,579) for the reasons as stated in previous Office actions and the further reasons below.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants arguments are persuasive with respect to claims 45-46, and 49-56 wherein specific genera of *Mortierella* are cultured at the conditions touted to produce specific unsaturated fatty acids. However, claims

Applicants' arguments are not persuasive regarding the production of any unsaturated fatty acid using any member of the subgenus *Mortierella*. The crux of applicants' arguments is that Suzuki only discloses the production of linolenic acid, the cultivation of certain species of *Mortierella* and the medium contains less calcium than the instant medium. However, the claims are not directed with any specificity to the particular strains within the species for which the higher productivities of specific unsaturated acids were obtained in the touted medium. There is no indication on the record that the increase in calcium ions would significantly affect the production of any or specific unsaturated fatty acid by members of the subgenus *Mortierella*, the members of which are not clearly delineated.

With respect to Applicant's argument that the references are not directed to members of the subgenus *Mortierella*, it is reiterated that applicant has not established that the study published in the Amano *et al.* reference is definitive to one of ordinary skill in this art regarding taxonomy of *Mortierella*. In any event the disclosure of Suzuki *et al.* regarding the adjustment of ions in the media is deemed relevant to the cultivation of any member of the genus *Mortierella*, regardless of the subgenus. In addition, Applicants have not demonstrated on this record that conditions suitable for strains of *Cunninghamella elegans* or *Aspergillus*, for example, are not suitable for *Mortierella*.

The unexpected results presented in the instant specification pertain to specific members of specific species, and not with any specificity to all members of the genus *Mortierella* or the subgenus *Mortierella*. There is no clear correlation between any results shown in the as-filed disclosure and the invention as claimed.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

Serial No. 09/331759
Art Unit 1651

-4-

Claims 45-46, and 49-56 are free of the art of record and would be allowable upon resolution of all 35 U.S.C § 112 issues.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
Art Unit 1651